NOT FOR PUBLICATION

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

THERAVANCE BIOPHARMA R&D IP, LLC, *et al.*, Plaintiffs, v. EUGIA PHARMA SPECIALTIES LTD., *et al.*, Defendants.	HONORABLE KAREN M. WILLIAMS Civil Action No. 23-926 (KMW-AMD) **OPINION**

APPEARANCES:

KATHERINE ANN ESCANLAR, ESQ.
ARNOLD B. CALMANN, ESQ.
SAIBER LLC
18 COLUMBIA TURNPIKE, SUITE 200
FLORHAM PARK, NJ 07932

Counsel for Plaintiffs Theravance Biopharma US, Inc., Theravance Biopharma Ireland Limited, Mylan Ireland Limited, and Viatris Specialty LLC.

R TOUHEY MYER, ESQ.
KRATZ & BARRY LLP
800 N. WEST STREET
WILMINGTON, DE 19801

Counsel for Defendants Eugia Pharma Specialities, LTD., Eugia US LLC, Aurobindo Pharma USA, Inc., and Aurobindo Pharma Limited.

DMITRY V. SHELHOFF, ESQ.
SHELHOFF CANFIELD & CHIN LLC
30 CHATHAM ROAD, SUITE 19
SHORT HILLS, NJ 07078

JAY P. LESSLER, ESQ.
BLANK ROME LLP
1271 AVENUE OF THE AMERICAS

NEW YORK, NY 10020
MICHAEL RAY DARBEE, ESQ.
BLANK ROME LLP
300 CARNEGIE CENTER, SUITE 220
PRINCETON, NJ 08540

Counsel for Defendants Mankind Pharma LTD. and Lifestar Pharma LLC

LOLY G. TOR, ESQ.
K&L GATES, LLP
ONE NEWARK CENTER
NEWARK, NJ 07102

Counsel for Defendants Cipla Limited and Cipla USA, Inc.

WILLIAMS, District Judge:

I. INTRODUCTION

This matter comes before the Court on Plaintiffs Theravance Biopharma R&D IP, LLC, Theravance Biopharma US, Inc., Theravance Biopharma Ireland Limited, Mylan Ireland Limited, and Mylan Specialty L.P.'s ("Plaintiffs") Motion to Exclude Defendants' "Impossibility" Arguments and Opinions from the Claim Construction Proceeding (ECF No. 331). Defendant Cipla Limited and Cipla USA, Inc.'s ("Cipla") opposed the motion (ECF No. 354), and Plaintiffs replied (ECF No. 372).

For the reasons that follow, the Court **GRANTS in part** and **DENIES in part** the pending Motion to Exclude (ECF No. 331).

II. BACKGROUND

In 2022, Cipla filed an Abbreviated New Drug Application (ANDA) No. 217958 with the U.S. Food and Drug Administration ("FDA"), seeking to get FDA's approval to make and use revefenacin in the U.S., a generic of the brand name drug Yupelri®, covered by several of Theravance's in-force U.S. patents listed in the Orange Book (OB) and other Theravance patents related to the OB patents. (*See* Am. Compl., ¶ 373, ECF No. 157.) The ANDA seeks a Paragraph IV certification (under Hatch Waxman, which is either a non-infringement or an invalidity assertion) to get FDA's approval to make/use these patents before their expiration date. (*Id.* at ¶¶ 181, 208, 374.) Cipla asserts patent invalidity, which if found, leads to a non-infringement finding.

On February 16, 2023, Theravance filed a Hatch-Waxman statutory infringement action against several generic manufacturers asserting that their ANDAs constituted patent infringement of certain OB and related patents covering Yupelri®. (*See* Compl., ECF No. 1.) Currently, Cipla

is the only defendant. (*See* ECF Nos. 403, 407.) Pursuant to Local Patent Rule 3.6(c), the original deadline for Defendants to serve invalidity contentions was November 10, 2023.[1]

On February 8, 2024, this Court entered an amended scheduling order setting an amended deadline for Defendants to serve their invalidity contentions for March 28, 2024. (ECF No. 209.) The Court further amended the deadline for Defendants to serve their invalidity contentions to April 18, 2024. (ECF No. 232.) Defendants thereafter served their invalidity contentions to Plaintiffs by April 18, 2024. (Decl. of Ty W. Callahan, Ex. 4, ECF No. 331-4.)

On February 28, 2025, Plaintiffs filed their Opening Claim Construction Brief ("Pls.' *Markman* Brief"). (ECF No. 310.) The same day, Defendants, including Cipla, jointly filed their Opening Claim Construction Brief ("Defs.' *Markman* Brief"). (ECF No. 312.) Defendants' *Markman* Brief asserted, for the first time, "impossibility" contentions relating to the '948 patent, claim numbers 4 to 21. (*Id.* at 18-20.) On April 18, 2025, the Parties filed their opposition briefs to their respective *Markman* briefs. (ECF Nos. 333, 335.) Defendants' opposition included a rebuttal declaration for their expert, Dr. Zaworotko. (ECF No. 337.) The same day, Plaintiffs filed the instant Motion to Exclude Defendants' "Impossibility" arguments and opinions from the Markman hearing, which is the subject of this Opinion. (*See* ECF No. 331-1.)

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[1] Local Patent Rule 3.6 provides: "(c) Not more than 30 days after the initial Scheduling Conference, each party opposing an assertion of patent infringement shall provide to each party asserting patent infringement the written basis for its 'Invalidity Contentions,' for any patents referred to in the opposing party's Paragraph IV Certification, which shall contain all disclosures required by L.Pat.R. 3.3.
(d) Any 'Invalidity Contentions' disclosed under L.Pat.R. 3.6(c), shall be accompanied by the production of documents required under L. Pat. R. 3.4(b) and (c).
(e) Not more than 30 days after the initial Scheduling Conference, each party opposing an assertion of patent infringement shall provide to each party asserting patent infringement the written basis for its 'Non-Infringement Contentions,' for any patents referred to in the opposing party's Paragraph IV Certification which shall include a claim chart identifying each claim at issue in the case and each limitation of each claim at issue. The claim chart shall specifically identify for each claim which claim limitation(s) is/(are) literally absent from each opposing party's allegedly infringing Abbreviated New Drug Application or New Drug Application.
(f) Any 'Non-Infringement Contentions' disclosed under L.Pat.R. 3.6(e), shall be accompanied by the production of any document or thing that each party who is an ANDA filer intends to rely on in defense against any infringement contentions by each party asserting patent infringement."

On April 29, 2025, U.S. Patent No. 12,285,417 ("'417 patent") issued with claims reciting methods for treating chronic COPD by administering a certain dosage of revefenecin to a COPD patient. (*See* Docket No. 25-cv-3790, Compl., ¶ 74, Ex. A.) On May 2, 2025, Plaintiffs filed another Hatch Waxman suit regarding the '417 patent. (*See id.*) On June 9, 2025, the Court consolidated Docket No. 25-cv-3790 into the instant action, Docket No. 23-cv-926, for all purposes, adding infringement of '417 patent to this action. (ECF No. 394.) The Court's consolidation terminated the 3790 action, obviating Defendants' filing infringement contentions against the '417 patent claims. (*See id.*)

III. LEGAL STANDARD

Local Patent Rule ("L.Pat.R.") 3.7 governs how amendments to invalidity contentions filed by the parties according to the Court's Schedule are to be made and states that:

> **Amendment of any contentions,** disclosures, or other documents required to be filed or exchanged pursuant to these Local Patent Rules **may be made only by order of the Court upon a timely application and showing of good cause.** The application shall disclose whether parties consent or object. Non-exhaustive examples of circumstances that may, absent undue prejudice to the adverse party, support a finding of good cause include: (a) a claim construction by the Court different from that proposed by the party seeking amendment; (b) recent discovery of material prior art despite earlier diligent search; (c) recent discovery of nonpublic information about the Accused Instrumentality which was not discovered, despite diligent efforts, before the service of the Infringement Contention; (d) **disclosure of an infringement contention by a Hatch-Waxman Act party asserting infringement under L. Pat. R. 3.6(g) that requires response by the adverse party because it was not previously presented or reasonably anticipated;** and (e) consent by the parties in interest to the amendment and a showing that it will not lead to an enlargement of time or impact other scheduled deadlines. The duty to supplement discovery responses under Fed. R. Civ. P. 26(e) does not excuse the need to obtain leave of Court to amend contentions, disclosures, or other documents required to be filed or exchanged pursuant to these Local Patent Rules. (emphasis added).

Simply, if a party wants to advance new invalidity contentions not previously set forth in their Invalidity Contentions, they must seek leave of the Court and show diligence and good cause why the contentions were not submitted within the period stated in the Court's Scheduling Order. (*See id.*)

IV. DISCUSSION

a. Plaintiffs' Motion to Exclude

As a preliminary consideration, the Court notes that Plaintiffs' Motion is timely. (*See* ECF No. 331-1.) This is because Defendants' *Markman* Brief—with new "impossibility" contentions—was filed on February 28, 2025. (*See* ECF No. 312.) Plaintiffs' Motion to Exclude these "impossibility" contentions was filed on the same date as its opposition to Defendants' *Markman* Brief: April 18, 2025. (ECF Nos. 331, 333.) In effect, Plaintiffs' Motion to Exclude is a distinct opposition to the relief sought in Defendants' *Markman* Brief.

In their Motion, Plaintiffs raise three grounds to exclude the arguments raised in Defendants' *Markman* Brief (ECF No. 312) at Section III (4)(a), pages 17-20 titled "The Indefiniteness Claims are Invalid Because They Recite an Impossibility" (the "impossibility contentions") from the *Markman* Hearing and subsequent *Markman* Opinion, as follows: (1) procedurally, that Defendants' insertion of their new "impossibility" contentions has not complied with the procedural requirements of the Local Patent Rules, as Defendants did not seek Court leave to add them; (2) substantively, that Defendants' expert, Dr. Zaworotko, is completely unqualified to opine on the inherent "impossibility" of claims 4-21 in the '948 patent, especially because he does not understand how inventions are recited through language nor the meaning and use of certain terms of art in claim language, for example, the meaning "wherein"; and (3) practically, that a grant of the current motion would not prejudice Defendants from raising their

"impossibility" contention in Fed. R. Evid. ("Rule") 702 motions regarding its experts' reports, or in Summary Judgment motions, or at trial, but would prejudice Plaintiffs at the *Markman* hearing. (*See* ECF No. 331-1.)

Plaintiffs' procedural argument is that Defendants' *timely* Invalidity Contentions raised on April 28, 2024 concerned only the following claims of the '948 patent: (i) independent claim 6; (ii) dependent claims 11-14, which depend on claim 6; and (iii) independent claim 17. (*Id.*) Defendants' specific invalidity contentions for these claims was that they are invalid under 35 U.S.C. § 112(1) (for lack of enablement in the specification) and (2) (for claim indefiniteness). (*See* ECF No. 333-1 at 5, 9 (citing Defendants' Invalidity Contentions Chart ("Defendants' Invalidity Chart") (ECF No. 331, Ex. 4)).) Specifically, no contention in Defendants' Invalidity Chart stated or implied these claims were "impossible" to practice but raised only 35 U.S.C. § 112 (1) written description and enablement issues and U.S.C. § 112 (2) indefiniteness contentions. (*Id.*)

In summary, Plaintiffs' procedural contention is that Defendants' *Markman* Brief asserted new invalidity contentions not raised before: that all claims of the '948 patent, claims 1 to 21, were "impossible" to practice because the claims recited a scientific impossibility, namely, that a dissolved crystalline freebase was characterized by X-ray diffraction values. (*Id.*) More to the point, Defendants assert only a crystalline solid can be characterized by X-ray diffraction values, and all claims of the '948 patent, each of which recite a dissolved crystalline freebase having certain X-ray diffraction values, are "impossible" to practice. (*Id.*) Because Defendants had not raised in their Invalidity Contentions the "impossibility" argument or mentioned that claims 4, 5, 7 to 10, and 15 to 21 of the '948 patent were invalid, Plaintiffs assert that Defendants did not raise *these* invalidity arguments timely in their Invalidity Contentions filed in April 2024. (*Id.*)

Therefore, Plaintiffs argue that Defendants should have sought this Court's leave to file new contentions and have been required to show diligence and good cause for bringing these contentions late. (*Id.*) Because Defendants did not follow this Court's procedure prescribed in its Local Patent Rules and therefore have not established the required diligence why these invalidity contentions have been filed ten months after the April 28, 2024 Invalidity Contentions, Defendants should be precluded from raising these new invalidity arguments at the upcoming *Markman* hearing.[2] (*Id.*)

b. Defendants' Opposition

In opposition to the instant Motion, Defendants raise two arguments: (1) procedurally, that their "impossibility" arguments are timely and should be considered in the *Markman* hearing (*see* ECF No. 354); (2) substantively, that their expert, Dr. Zaworotko, understood the meaning of "wherein" and of claim indefiniteness, and opined that scientific principles confirm the '948 patent claims are indefinite. (*Id.*) In sum, Defendants' procedural argument is that their "impossibility" contentions are not new and that Plaintiffs mischaracterize Defendants' "impossibility" contentions because Defendants had properly set them forth in their April 18, 2024 Invalidity Contentions. (*Id.*; *see* ECF No. 232.) Specifically, Defendants aver that they alerted Plaintiffs to their "impossibility" arguments regarding claims 6, 11-14, and 17 of the '948 patent in their April 18, 2024 Invalidity Contentions and therefore they did not need to seek leave under L.Pat.R. 3.7 to file their "impossibility" contentions, and thus did not breach that local rule.[3] (ECF No. 354.)

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[2] Plaintiffs further argue that Defendants' cited case of *Taro Pharm. Indus. Ltd. v. Novitium Pharma, LLC,* 19-cv-01028 (FLW), by which Defendants argue that their new contentions had already been disclosed, is inapposite and cannot support Defendants' arguments.

[3] Defendants further argue that Plaintiffs' cited case of *Aptalis Pharma US Inc. v. Mylan Pharmaceuticals, Inc.*, 13-cv-04158, 2014 WL 12784473 (D.N.J. June 20, 2014) is inapposite to this Motion. Defendants argue that the *Aptalis* facts do not apply here because, as Defendants argue, the *Aptalis* defendant—Mylan— had disclosed no invalidity contentions *at all* before seeking leave from the court to serve the plaintiffs with those contentions. *Id.* That is, Mylan

c. Analysis of Contentions

The Court focuses on the Parties' procedural dispute as a procedural resolution here settles the current Motion most economically and with the least prejudice to either party. As a result, the Court reviews neither the Parties' substantive arguments regarding the qualifications of Dr. Zaworotko, his expert testimony, nor the substance of his arguments but leaves the dispute about the alleged unreliability of Dr. Zaworotko's testimony to Rule 702 motions, Summary Judgment Motions, or to trial. In addition, the Court's resolution of the Motion before the *Markman* hearing does not prejudice Defendants because their substantive arguments regarding the "impossibility" of the '948 claims are preserved for a more appropriate procedural route.

The Court finds that, since Defendants filed their Opening Claim Construction Brief (*Markman* Brief) on February 28, 2025, long past this Court's Scheduling Order April 18, 2024 deadline for asserting invalidity contentions, the addition of their new "impossibility" contentions in their *Markman* Brief without seeking leave do so violates both this Court's Scheduling Order and L.Pat.Rule 3.7. For that reason, Defendants' invalidity contentions in their *Markman* Brief will **not** be discussed at the *Markman* Hearing or in the follow-on *Markman* Opinion. (*See* Defs.' *Markman* Brief at 17-20.) Nor will this Court permit Dr. Zaworotko or any party or witness at the *Markman* hearing to discuss arguments regarding "impossibility" contentions or new indefiniteness contentions of the claims of the '948 patent.

To determine whether Defendants inserted new contentions into their *Markman* brief (ECF No. 312, filed 10 months after the deadline for Invalidity Contentions), the Court compares Defendants' Invalidity Contentions of April 18, 2024 (ECF No. 331, Ex. 4 (Defendants' Invalidity

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was late serving Aptalis its invalidity contentions, which is exactly opposite of the fact here, namely, that Defendants had timely served Plaintiffs their invalidity contentions for the '948 claims on April 28, 2024. (*See* ECF No. 354.)

Contentions Chart, Filed Under Seal) ("Defendants' Chart")) with Defendants' invalidity arguments in their *Markman* Brief (ECF No. 312).[4] *See* Table 1, *infra*.

TABLE 1. Comparison of Defendants' Invalidity Contentions from Defendants' Chart and Defendants' *Markman* Brief Regarding the '948 Patent

Claim	From Defendants' Invalidity Contentions Chart of April 18, 2024 (ECF No. 331-4, under Seal)	From Defendants' *Markman* Brief filed February 28, 2025 (ECF No. 312 at 18-20)
1-17, 19, & 21	**Indefinite for different reason**[5] (35 U.S.C. § 112(2) (pre-AIA) ECF No. 331-4 at 4-5 states these claims are indefinite under § 112(2) for lack of recitation of particular X-ray source, which is not the same contention under § 112(2) as stated in Defendants; *Markman* Brief. *See* the adjacent cell.	**Indefinite under § 112(2) and Impossible under 35 U.S.C. § 101** Defendants stated in their *Markman* brief: (ECF No. 312 at 19) "The claims are impossible AND Indefinite."… "Each of these claims recites a solution that must be construed as containing no X-ray diffraction markers of solid crystalline revefenacin." **Defendants' *Markman* Brief asserted indefinite and impossible contentions for ALL CLAIMS of the '948 patent, but *Markman* Brief indefiniteness contention differs from that in Defendants' Invalidity Contentions.** Plaintiffs were therefore not earlier apprised of the indefiniteness contention put forth in the *Markman* Brief.
1-21	**Lack of Enablement** (35 U.S.C. § 112(1) (pre-AIA) ECF No. 331-4 at 3 states all claims of the '948 patent are invalid for lack of enablement.	**Indefinite under § 112(2) and Impossible under 35 U.S.C. § 101**
6 (Independent) A pharmaceutical composition comprising: a dissolved	**Indefinite under § 112(2)** ECF No. 331-4 at 4 states this claim is indefinite under § 112(2) because a dissolved crystalline freebase does not	**Indefinite under § 112(2) and Impossible under 35 U.S.C. § 101**

[4] Mindful of the confidential nature of Defendants' Chart, the Court only summarizes, not cites, from it.

[5] 35 U.S.C. § 112 (pre-AIA), states in relevant part:

"The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention. **[(This is paragraph 1, commonly termed § 112(1) (pre-AIA)** (emphasis added)].

The specification shall conclude with one or more claims **particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention. [(This is paragraph 2, commonly termed § 112(2) (pre-AIA))** (emphasis added)]. . . ."

crystalline freebase of … [a certain ester] and an aqueous pharmaceutical carrier; wherein the crystalline freebase is characterized by a powder x-ray diffraction pattern comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1; and wherein the pharmaceutical composition has a pH of about 5.	exhibit discrete XRPD peaks (*i.e.*, 2θ values), which suggests the scope of claim 6 cannot be ascertained with reasonable certainty.	
11-14, (depend from 6) 11. Claim 6, plus the pharmaceutical composition is isotonic. 12. Claim 6, plus the pharmaceutical composition is buffered with citrate buffer to a pH of about 5. 13. Claim 6, wherein the pharmaceutical composition contains about 0.05 µm/ml to about 10mg/ml of the [certain ester]. 14. Claims 6, wherein the pharmaceutical composition is administered using a nebulizer inhaler.	**Indefinite under § 112(2)** For the same reasons as stated above for claim 6.	**Indefinite under § 112(2) and Impossible under 35 U.S.C. § 101**
17 (Independent) A pharmaceutical composition comprising a solution of a crystalline freebase	**Written Description and Lack of Enablement Under § 112(1)** ECF No. 331-4 at 4 states that the "characterized by" limitation is invalid:	**Indefinite under § 112(2) and Impossible under 35 U.S.C. § 101**

of … [a certain ester] characterized by (i) a powder x-ray diffraction pattern comprising diffraction peaks at 2θ values of 6.6±0.1, 13.1±0.1, 18.6±0.1, 19.7±0.1, and 20.2±0.1 or a melting point of about 125°C.	- for **lacking written description** because the specification discloses only a single freebase of revefenacin, AND -for **lack of enablement** for not teaching a POSITA to make/use other forms of revefenacin having the recited XRPD peaks.	
18 (Independent)	**No Contention**	**Indefinite under § 112(2) and Impossible under 35 U.S.C. § 101**
20 (Independent)	**No Contention**	**Indefinite under § 112(2) and Impossible under 35 U.S.C. § 101**

From Table 1, the Court finds that Defendants did timely raise invalidity contentions against claims 6 and 11-14 under 35 U.S.C. § 112(2) pre-AIA for indefiniteness of the claim language, and against claim 17 under 35 U.S.C. § 112(1) pre-AIA for lacking written description and enablement. The issue is whether the "impossibility" contentions in Defendants' Chart are a different kind than those previously raised under § 112(1) or § 112(2). If the "impossibility" contentions are the same kind as previously raised for claims 6, 11-14, and 17 under § 112(1) or § 112(2), then the inquiry ends; the Court would find Defendants have not raised new invalidity contentions. If the "impossibility" contentions are not the same kind, then the Court finds that Defendants have improperly inserted new invalidity contentions without having obtained the required leave and without having shown the required diligence and good cause.

To clarify the difference between "impossibility" contentions and indefiniteness contentions under § 112(2) pre-AIA, the Court looks to jurisprudence from the Supreme Court and the Federal Circuit. The Supreme Court has pronounced generally that the standard of claim definiteness and indefiniteness: "mandates clarity, while recognizing that absolute precision is unattainable. The standard we adopt accords with opinions of this Court stating that '*the certainty which the law requires in patents is not greater than is reasonable*, having regard to their subject-

matter.'" *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014) (quoting *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261, 270 (1916)) (emphasis added).

The Federal Circuit has taught more specifically: "Whether a claim is *invalid for indefiniteness requires a determination whether those skilled in the art would understand what is claimed when the claim* is read in light of the specification." *Takeda Pharm. Co. v. Zydus Pharms. USA, Inc.*, 743 F.3d 1359, 1366 (Fed. Cir. 2014) (emphasis added).

Regarding the standard for the lack of enablement, the *Takeda* Court has also taught: "It is well established that the 'enablement requirement is met if the description enables *any* mode of making and using the invention.'" *Id.* at 1366 (quoting *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998)). Thus, from these cases, and as the Parties' contentions indicate, an indefiniteness invalidity contention is not the same as an enablement invalidity contention because each contention has a different standard for demonstrating validity/invalidity. Moreover, the standard for indefiniteness is not the same as the standard for an "impossibility" contention. In fact, the Federal Court has held that it is enablement, not indefiniteness, which is "closely related to the requirement for utility." *In re McLeay*, 2015 WL 516809 at *3 (Fed. Cir. Feb. 18, 2025) (quoting *In re '318 Pat. Infringement Litig.*, 583 F.3d 1317, 1323 (Fed. Cir. 2009)). Even more to the point, the Federal Circuit has clarified that:

> Lack of enablement and absence of utility are closely related grounds of unpatentability. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 956, 220 USPQ 592, 596 (Fed. Cir. 1983). The enablement requirement of 35 U.S.C. § 112, ¶ 1 requires that the specification adequately discloses to one skilled in the relevant art how to make, or in the case of a process, how to carry out, the claimed invention without undue experimentation. *See Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997). *The utility requirement of 35 U.S.C. § 101 mandates that any patentable invention be useful and, accordingly, the subject matter of the claim must be operable. See Brooktree*

> *Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 USPQ2d 1401, 1412 (Fed. Cir. 1992). If a patent claim fails to meet the utility requirement because it is not useful or operative, then it also fails to meet the how-to-use aspect of the enablement requirement.

Process Control Corp. v. HydReclaim Corp., 190F.3d 1350, 1358 (Fed. Cir. 1999) (emphasis added).

Defendants contend in their *Markman* Brief that all claims of the '948 patent are "impossible and indefinite." (*See* Defs.' *Markman* Brief at 19-20.) From the above guidance, the Court appreciates that an indefinite invalidity contention, having a different standard than that for lack enablement, is not related to an "operability" or "impossibility" standard. That is, an assertion that a claim is impossible is not grounded in 35 U.S.C. § 112(2) but in 35 U.S.C. § 101, the requirement that all patented inventions be useful, *i.e.*, operable. In Defendant's *Markman* Brief (*see* Table 1, *supra*), Defendants contend that all '948 claims—including 6, 11-14, and 17—are both impossible and indefinite, meaning all '948 claims violate not just § 112(2) but also § 101, for lack of utility. To be clear, and in accord with Federal Circuit guidance, the Court does not conflate the impossibility and indefiniteness contentions—they are distinct.

Since "impossibility" contentions are not indefiniteness contentions, Defendants' *Markman* Brief of February 2025 does not accord with, but oversteps, their Invalidity Contentions of April 2024, where Defendants stated that Claims 6, 11-14, and 17 were invalid for indefiniteness as well as Claim 17 was invalid for lack of written description and enablement. (*See* Table 1, *supra.*) The impossibility—lack of operability/utility—contentions for all '948 claims were not suggested, implied, or adumbrated in Defendants' Invalidity Contentions of April 2024, and are therefore new. *See* 35 U.S.C. § 101. Simply, Defendants have tagged all other '948 claims, besides those in the Invalidity Contentions, with not only an indefinite contention, but with a double

contention: indefinite and impossible, by which Defendants expanded without leave their original invalidity contentions. That is, Defendants went from contending five (5) claims of the '948 patent were invalid under 35 U.S.C. § 112, to asserting all twenty-one (21) claims of the '948 patent are both indefinite under U.S.C. § 112(2) and "impossible" or inoperable under 35 U.S.C. § 101. Clearly, Defendants' *Markman* Brief expresses new contentions that Defendants have not sought leave to add under the Local Patent Rules.

In addition, the Court finds that Defendants' reliance on *Taro Pharmaceutical Industries Ltd. v. Novitium Pharma LLC*, No. 19-cv-01028 (FLW), 2020 WL 1673045, at * 5 (D.N.J. April 6, 2020) to justify these new contentions is misplaced. (*See* Defs.' Opp. Br. at 7-8, ECF No. 354.) The *Taro* Court found that, even though Defendant had not listed in its Invalidity Contentions "all claims in which *the disputed term appeared*,"[6] *Taro* would not suffer prejudice by Novitium's adding an indefiniteness argument to previously unmentioned patent claims. *Id.* at *5. The Court's reasoning was that the newly added claims had the same disputed limitation and the same legal theory of invalidity—indefiniteness—as Novitium had argued in its Invalidity Contentions. *Id.* Thus, the *Taro* Court concluded that Novitium had sufficiently noticed Taro of its invalidity contentions because the "new" contentions were exactly the same as the "old" ones. *Id.*

That is not the situation here. Defendants have added a new legal theory of "impossibility" to claims previously not discussed in their Invalidity Contention which, as discussed above, is not an indefiniteness contention. Plus, Defendants have added an indefiniteness contention to claims not previously mentioned in their Invalidity Contentions and which do not recite the same limitations. Defendants are wrong that *Taro* applies here. *Taro* does not stand for the proposition

[6] Specifically, in its *Markman* Brief, Defendants added invalidity contentions for two claims in one patent and three claims in another patent, which they had not expressly mentioned in their formal Invalidity Contentions.

that the legal theory of indefiniteness applied to independent claim 6 can extend to all independent claims of the '948 because Defendants' scientific theory under the indefiniteness contention is the same, namely, that a dissolved crystalline freebase cannot exhibit X-ray diffraction values. (*See* Table 1, *supra*.) For *Taro* to apply, the same claim limitation must be recited in all claims not previously discussed, mentioned, or implied in Defendants' Invalidity Contentions. *See Taro*, 2020 WL 1673045, at * 5. As that is not the case here, *Taro* is of no import.

Moreover, the Court finds Plaintiffs citation to *Aptalis Pharma US Inc. v. Mylan Pharmaceuticals, Inc.*, No. 13-cv-04158, 2014 WL 12784473 (D.N.J. June 20, 2014), is on point here. In *Aptalis,* even though Mylan had sought leave to add invalidity contentions after the Scheduling Order deadline because it had not submitted any contentions at all, the Court found Mylan had neither exercised diligence nor showed good cause in adding contentions after the scheduling deadline, as required by L.Pat.R. 3.7.[7]

[7] In *Aptalis,* Mylan filed a motion to add new invalidity contentions regarding Aptalis' intended use of the word "about" in the relevant claims. But even though Mylan was following Pat. Loc. R. 3.7 to do so, this Court refused Mylan's motion because Mylan had so much time to consider, ponder, and review Aptalis' intended meaning of the disputed term "about" and therefore Mylan's new contentions had not been diligently filed and would prejudice Aptalis both because of adding an additional burden to respond to the new contentions and because Mylan's "sandbagging" prejudiced *Aptalis* without good cause.

The *Aptalis* Court stated: "By the time Mylan was preparing its Invalidity Contentions, it had studied the patents, their prosecution histories, and the prior art it had uncovered to date. *See, e.g.*, Notice of Paragraph IV Certification Regarding U.S. Patent No. 8,217,083, Opp. Exhibit B. It had also received Aptalis's disclosure of asserted claims, each of which recites the term "about" either directly or indirectly. As Mylan admits, Aptalis's disclosure copied, word-for-word, the language of the asserted claims and also cited Mylan's ANDA. Thus, Mylan's most direct evidence as to what the claims mean, at the time it prepared its contentions, was the claims themselves as issued by the U.S. Patent Office and repeated by Aptalis. Still, Mylan urges that it could not have anticipated that Aptalis might take the position that 'about' means 'approximately.' According to Mylan, both the plain and ordinary meaning of 'about' and 'approximately' suffer from the same defect of failing to provide objective limits as to the range encompassed by the term. Mylan Req. at 6 ('Because the claim elements that include the word "about" are close to the prior art, not construing the term "about"—or giving the term its plain and ordinary meaning—would leave Mylan—and any other alleged infringer—without knowledge as to where the bounds of the claims fall.') *This argument only crystallizes the weakness of Mylan's position insofar as it concedes that Mylan did not anticipate that Aptalis might adopt a plain and ordinary meaning of 'about.'* Had it, Mylan presumably would have perceived its need to raise the indefiniteness arguments it seeks leave to add now." *Aptalis,* 2014 WL 12784473 at *5 (emphasis added).

Here, unlike in *Aptalis,* Defendants had already filed Invalidity Contentions but by-passed L.Pat.R. 3.7 by not seeking permission to add to their *Markman* Brief the "impossibility and indefiniteness contentions" for claims not previously mentioned and which did not claim the same limitations but included only a similar scientific concept of a dissolved crystalline freebase. It is not clear whether Defendants did not appreciate their "impossibility" theory implied a different legal ground of invalidity, *i.e.*, a lack of utility, not indefiniteness; or whether Defendants' confidence that *Taro* supported their legal theory afforded them license to add new claims to their invalidity contentions. Regardless, the Court finds that Defendants have prejudiced Plaintiffs by burdening them with the impetus for filing this Motion on top of the parties' abundant burden of opposing each other's arguments relating to disputed claim terms.

The Court finds that, in order for Defendants to add new "impossibility" (and indefinite) contentions for claims previously unmentioned in their Invalidity Contentions that do not recite the same claim limitations, Defendants should have sought leave from the Court. By not adhering to the proper procedure, Defendants have not met their burden of showing diligence or good cause for adding new invalidity contentions for the '948 claims, as required under L.Pat.R. 3.7.

Accordingly, the Court grants Plaintiffs' Motion (ECF No. 331) to exclude from the *Markman* hearing any discussion of Defendants' "impossibility" arguments as set forth in Defendants' *Markman* Brief (ECF No. 312) at Section III (4)(a), pages 17-20, including the part titled "The Indefiniteness Claims are Invalid Because They Recite an Impossibility." For clarity, the invalidity contentions of the '948 claims that are specifically excluded from the *Markman* hearing are:

- For claims 1-21 of the '948 patent: that these claims are "impossible" because Defendants' Invalidity Contentions did not express that these claims are "impossible," and

- For claims 1-5, 7-10, 15-21 of the '948 patent: that these claims are indefinite for the reasons described in Table 1, *supra*, because Defendants' Invalidity Contentions were silent as to these claims.

Moreover, neither Dr. Zaworotko nor anyone else may discuss or raise at the upcoming *Markman* hearing these arguments: (1) the "impossibility" arguments for claims 1-21 of the '948 patent as set forth in Dr. Zaworotko's declarations, expert reports, or Defendants' *Markman* Brief; or (2) that claims 1-5, 7-10, 15-21 of the '948 patent are indefinite under 35 U.S.C. § 112(2) (pre-AIA).

Even though the "impossibility" arguments are not properly before the Court in the upcoming *Markman* hearing nor will be discussed there or in the subsequent *Markman* Opinion, these arguments may be raised in a Summary Judgment motion, a Fed. R. Ev. 702 motion, or at trial, where they can be reviewed properly under the relevant standards. Further, relating solely to Plaintiffs' procedural arguments about Defendants non-compliance with the Local Patent Rules, this decision does not raise or opine on the Parties' substantive arguments for this Motion regarding Dr. Zaworotko's opinions on "impossibility" of the relevant claims.

V. CONCLUSION

For all the foregoing reasons, the Court **GRANTS in part** and **DENIES in part** Plaintiffs' Motion to Exclude (ECF No. 331). An order consistent with this Opinion will be entered.

Dated: August 6, 2025

KAREN M. WILLIAMS
UNITED STATES DISTRICT JUDGE